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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,549	11/28/2003	Veronica Rose Hargis		3319
7590	11/20/2006		EXAMINER	
DR. LUTHER CALVIN HARGIS 40 MAPLE AVE. WARWICK, NY 10990			PATEL, TARLA R	
			ART UNIT	PAPER NUMBER
				3772

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/724,549	HARGIS ET AL.
	Examiner Tarla R. Patel	Art Unit 3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 28 November 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) 1 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 1(d) objected to because of the following informalities:  
Applicant's needed to clarify if the dome in statement (d) and dome/shield in statement (a) are same. Appropriate correction is required.
2. Claim 8 the recitation of "said attachment means" is never recited in claim 3 or claim 1, from which claim 8 depend. Clarification is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 6,9 and 11 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. With respect to claims 6,9 and 11 the inventor does not specify the dome to have a width and breath of five-millimeter. With respect to claim 9, the specification does not support the shell or base being composed of a material having a gauge of approximately 1/16-inch thickness; with respect to claim 11, the specification does not support the device being 1.5 to 2 ounces in weight as originally filed.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,2,4,10 and 12 rejected under 35 U.S.C. 102(b) as being anticipated by Cox (5,672,150).

Cox discloses a thermoplastic (column 3 line 25) shell splint or brace for the carpal tunnel. The apparatus discloses a support and protective shield/dome (12) overlying the carpal tunnel of the wrist, first securing (6) means for reasonably the support means to the hand securing by strap that comprises Velcro closure (column 3 line 42), and wherein the thin shell is

formed of a rigid material fitted to the human hand and forearm to rest upon the thenar, Hypotenar, lateral distal wrist and proximal forearm (see fig 1) as required by claim 2 and 4.

With respect to claim 10 the domed portion of the mid section which is raised above the tunnel and is generally linear along the longitudinal and transverse axes and is curvilinear in a direction normal to the axes to support the hand in a neutral position (see fig 1).

With respect to claim 12 the apparatus is contoured to a minimal area of the palm, wrist and forearm to allow for a greater range of motion while protecting the carpal region (column 2 lines 25-28).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 6,7,9 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (5,672,150).

With respect to claim 6 Cox substantially disclosed the invention as claimed; see rejection to claims 1-2,4,10 and 12 above, however Cox does not disclose the raised dome have width and breath of the approximate five millimeters. At the time of the invention, it would have been an obvious matter of design choice to modify the dome of Cox's device to have width and breath of the approximate five millimeters, since applicant has not disclosed that having the this specific size is for any particular purpose to have it.

With respect to claim 7 Cox substantially disclosed the invention as claimed; see rejection to claim 6 above, and also teaches device said dome curves downward and outward to contact the proximal base of the hand just forward of the mid wrist crease, laterally the outer borders of the volar wrist just outside the lateral borders of the anatomic carpal tunnel, and rearward the forearm just proximal to the anatomic carpal tunnel area (see fig 1), wherein the apparatus is contoured to follow the natural conformation of the palm, wrist and hand.

With respect to claim 9 Cox substantially disclosed the invention as claimed; see rejection to claims 1,2,4,10 and 12 above, however Cox does not disclose the shell or base having the thickness of approximately 1/16

inch. At the time of the invention, it would have been an obvious to one skilled in art to make the shell or base of Cox to approximately the 1/16 inch thickness, such that it would be easy to move the wrist with device on user wrist and it would not be a obstruction when it is placed on user wrist.

With respect to claim 11 Cox substantially disclosed the invention as claimed; see rejection to claim 7 above and also teaches device being lightweight and made of pliable material (column 2 line 38-46), however Cox does not disclose the device being 1.5 to 2 ounces in weight. At the time of the invention, it would have been an obvious to one skilled in art to interpret pliable material to rigid. Also to make device of Cox at 1.5 to 2 ounces in weight to easy to carry around and not to be feeling heavy and cumbersome around user's wrist.

5. Claims 3 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Cox as applied to claims 1-2,4,6-7,9-12 above, and further in view of Singer (6,120,472).

Cox substantially disclosed the invention as claimed; see rejection to claims 1,2,4,10 and 12 above, however Cox does not disclose the apparatus with two straps secured to the lateral margins of the brace to the dorsal area of the wrist by a buckle/Velcro closure to secure the brace.

However Singer teaches a brace with two straps secured to the lateral margins of the brace to the dorsal area of the wrist by a buckle/Velcro closure to secure the brace (see fig 5a).

At the time of the invention, it would have been an obvious to one skilled in art to have to modify the brace of Cox with two Velcro/buckle strap assembly to have better secure the brace around the user's wrist.

6. Claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over Cox as applied to claims 1,2,4,10 and 12 above, and further in view of Houser (App. No. 09,965,542).

Cox substantially disclosed the invention as claimed; see rejection to claims 1,2,4, 10 and 12 above, however Cox does not disclose the apparatus including perforation by small holes in the dome for ventilation of the user's skin.

However Houser teaches a brace for supporting a wrist, wherein the brace is made with perforations to wick away sweat and provide path for air to enter (0074).

At the time of the invention, it would have been an obvious to one skilled in art to have made the brace of Cox to include the perforations as taught by

Houser, such that perforation would allow for air to enter and sweat to be wicked away.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tarla R. Patel whose telephone number is 571-272-3143. The examiner can normally be reached on M-F 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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